

Session Name: Shifting a Small Agency's Mission to Embody Customer Service
1:40 PM Session

Moderator: Karen Brown, EPA HQ

Speaker: Audrey Borja, Food and Drug Administration

Main Points

- * Bringing the role customers into achieving the DCA mission
- * Differences between compelled customers of regulatory agencies and customers of service providers
- * Since HQ can't create culture change in the field, what can you do to engage field office personnel in shifting to a customer focus?

Presentation Summary:

- * Reasons for initiating Customer Service in FDA:
 - EO 12862 - Setting Customer Service Standards
 - Presidential memo, 3/22/95 - Improving Customer Service
 - Presidential memo, 3/3/98 - Conducting "Conversations with America" to Further Improve Customer Service
- * Needed to define what is a customer. FDA set-up new office to address customer service. Made part of strategic planning. Big paradigm change was needed
- * Customers are those who use or are directly affected by our product/service
- * Performed survey of four major customer groups (regulatory, health organizations, public, government) to get feedback on FDA operations. Made changes based on feedback. Received over 50 Hammer Awards for improvements made.
- * Based on relationships, customers can be categorized into: voluntary customers, entitled

- * Manages resources well
- * Problem solving/remove barriers
- * Prompt handling of complaints

- * Listens well
- * Reliability, trustworthiness
- * Timeliness

* All FDA Customers are entitled to:

- * Fair, courteous and professional treatment
 - * Information that is accurate and current
 - * Timely responses to request
 - * Reasonable access to appropriate staff
 - * Confidence that effects are made to assure that regulated products in the marketplace
- are in compliance with FDA laws and regulations
- * Two-way communication
 - * Opportunities for collaboration and partnerships
 - * Participation in the agency's decision-making process
 - * Consideration of their opinions and concerns by the agency

* Other government agencies are entitled to:

- * Cooperation from the FDA in maximizing efficient use of resources, eliminating duplication of efforts and carrying out collaborative efforts
- * Technical assistance, training and guidance

* Regulated industry is entitled to:

- * Timely review of product applications
- * Professional treatment in resolving disputes
- * Fair application of laws and regulations in enforcement activities
- * Fair and consistent inspections and product application reviews
- * Respect in the agency's performance of duties and responsibilities

* FDA rewarded their inspectors on the number of facilities that were in compliance, not the number of enforcement cases they took. Inspectors used a data base call "CARS" - compliance achievement reporting system, to help track their inspections. CARS significantly reduced the review of the inspections.

Key Questions:

Q: What has FDA done to streamline/improve drug processing approval?

A: Process has been improved through reorganizing into specialty teams

Q: Run into problems with public objecting to quicken review times?

A: Yes - have to balance

Q: How did FDA make the paradigm shift from enforcement to compliance?

A: Top down appraoc

How can EPA use this information:

* Start making the paradigm shift - treat our states and regulated community like customers.

* Reward compliance numbers, not just enforcement. Stress that compliance is the key, not enforcement numbers.

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